REMARKS

After entry of this amendment, claims 1, 2, and 4–15 are pending. Claims 11–15 are withdrawn from consideration.

Amendments to the Claims

Claims 16–25 have been canceled without prejudice.

Claims 1 and 10 have been amended to delete "means for adjustably moving" and to insert -- is adjustably movable --.

Claim 11 has been amended to replace "moving means comprises" with -- first housing portion and the second housing portion comprise --.

Objections to the Claims

Claims 1 and 10 stand objected to as falling within 35 U.S.C. § 112, sixth paragraph without explicit recitation in the Specification of the structures, materials, and/or acts falling within the means plus function element. Applicants submit that the objections are moot in view of the amendments to claims 1 and 10.

Objections to the Specification

The Specification stands objected to as lacking explicit recitation of the structures, materials, and/or acts falling within the means plus function elements in claims 1 and 10. Applicants submit that the objection is moot in view of the amendments to claims 1 and 10.

Rejections Under 35 U.S.C. § 112

Claims 1, 6, and 10 stand rejected under 35 U.S.C. § 112, first paragraph as not enabled. In particular, the Examiner characterizes the Specification as not listing non-compressible gels 72*a*. Applicants refer to the Specification on page 3, lines 3–6 as disclosing that suitable non-compressible gels are disclosed in International Application No. PCT/US01/29682, filed on September 21, 2001 and entitled "Surgical Access Apparatus and Method". This application published as International Patent Publication No. WO 2002/034108 A2 on May 2, 2002. Suitable gel materials are described from page 14, line 5 to page 18, line 13 of the publication. Applicants submit that the material incorporated by reference is non-essential because non-compressible gel materials are adequately described in the application, for example, in the Specification from page 2, line 19 to page 3, line 6, as well as in the drawings in FIGS. **6**, **7**, **16**, and **17**. Consequently,

claims 1, 6, and 10 are enabled either with or without the subject matter incorporated-by-reference.

The Examiner further requests clarification of how a non-compressible gel material deforms to a different shape. The Examiner appears to be conflating compressibility and deformability.

"Compressible", when used to describe a material, refers to a change in volume of the material in response to a change in pressure. Foam is a common compressible material: applying pressure to the foam reduces its volume. Gases are typically compressible, as demonstrated by the ideal gas law $PV=nRT$ in which increasing the pressure (P) decreases the volume (V). Many liquids are incompressible, however, for example, water and hydraulic fluids. Water in a plastic bag is deformable, but remains incompressible: changing the shape of the bag does not change the volume of the water. Similarly, hydraulic breaking systems for cars depend on the incompressibility of the brake fluid: applying the break pedal applies pressure to the break fluid, which transmits the pressure to the brake calipers at the wheels. Although the shape of the fluid changes as the brake fluid travels from a reservoir, into brake lines, and into cylinders in the brakes at the wheels, the volume does not.

"Deformable", on the other hand, refers to a reshapablity of a material. Many incompressible materials are deformable, for example, a piece of copper wire.

For example, in the embodiments illustrated in FIGS. **7** and **17** of the present application, the gel **72***a* is both non-compressible and deformable. Because the volume of the gel **72***a* does not change in response to an applied pressure, the valve **50** comprises an expansion cavity or space **105***a* and **105**, respectively, into which the gel is displaced. Accordingly, non-compressibility and deformability of a gel are not mutually exclusive. For at least these reasons, Applicants request that the Examiner withdraw this rejection.

Rejections under 35 U.S.C. § 103

Obviousness is a question of law based on underlying factual inquiries set forth in *Graham v. John Deere*: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the claimed invention and the prior art; and (3) resolving the level of ordinary skill in the pertinent art. Objective evidence of non-obviousness must be also considered. In assessing the differences between the claim and the cited references, every feature of the claim must be disclosed or suggested in the cited references or known to one skilled in the

art in making a *prima facie* case of obviousness. *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003). A *prima facie* case of obviousness also requires a reasonable expectation of success in the modification or combination of references, which must be found in the cited references or must be known to one skilled in the art. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Claims 1, 2, and 4–10 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 4,143,853 (Abramson), in view of U.S. Patent No. 5,460,616 (Weinstein). The Examiner relies on Abramson for disclosing every feature recited in the rejected claims, except for a gel material, for which the Examiner relies on Weinstein.

Independent claims 1 and 10 recite in part "the proximal housing portion is adjustably movable axially relative to the distal housing portion". The Examiner refers to a ridge **31** and groove **32** illustrated in FIGS. **1–5** of Abramson as corresponding to the recited axial adjustability. In fact, the cylindrical male member **11** and the cylindrical female member **12** in Abramson are not relatively adjustable. Abramson discloses, "Moreover, the valve, once assembled, cannot be disassembled, misadjusted, or tampered with in any way." Abramson 3:48–50. The catheter valve **10** is not adjustable in any way. Instead, FIG. **5** simply illustrates the catheter valve **10** and a disassembled state, with FIGS. **1** and **3** illustrating the catheter valve **10** in assembled state. Accordingly Abramson does not disclose this feature.

Each of independent claims 1, 6, and 10 recites "a gel". The Examiner relies on Weinstein as disclosing a gel. Weinstein discloses a spheroidal valve member **24** comprising a spheroidal inner container **28** filled with a silicone or petroleum jelly **30**. Weinstein at 2:64–3:7, FIG. **1**. Weinstein refers to the silicone or petroleum jelly **30** as a gel. The gel of Weinstein is not the gel recited in claims 1, 6, and 10, however.

Claims 1 and 10 recite in part "the gel having characteristics for creating a pressure on the instrument to form a seal with the instrument". Weinstein does not disclose or suggest that either the silicone or petroleum jelly **30** disclosed therein have this property. Instead, Weinstein discloses, "the deflected leaves **34** of the tricuspid valves **26, 27** are shown, which fold around the catheter **32** (and the dilator stylette before catheter) to provide sealing." Weinstein at 3:24–27. Consequently, the tricuspid valves **26** and **27** seal the catheter **32**. Although Weinstein states that the silicone or petroleum jelly **30** may assist the tricuspid valves **26** and **27** (Weinstein at 3:37–40), Weinstein does not disclose or suggest that applying pressure on the silicone or

petroleum jelly **30** forms a seal with the catheter. Accordingly, Weinstein does not disclose this property.

Claim 6 recites in part:

> a subassembly including the seal material disposed in the gel cavity, the seal material being configured with the channel in an open state; and
>
> a second housing portion disposed in juxtaposition to the first housing portion and applying a force to the seal material in the subassembly, the force being of a magnitude sufficient to place the channel of the seal material in a closed state

The Examiner does not describe- Weinstein disclosing or suggesting this feature, either alone, or in conjunction with Abramson.

Because Abramson and Weinstein do not disclose or suggest every feature recited in independent claims 1, 6, and 10, these claims are patentable over the cited references. Because claims 2, 4, and 5 are dependent on claim 1, and claims 7–9 are dependent on claim 6, these claims are also patentable over the cited references for at least the same reasons.

Rejoinder of Withdrawn Claims

Because all claim 10 is allowable over the references of record, Applicants request rejoinder of withdrawn claims 11–15 and allowance of the same.

No Disclaimers or Disavowals

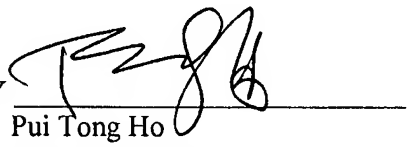
Although the present paper may include a combination of alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding that previously pending claims in this application are not patentable over the cited references. Rather, any alterations and/or characterizations are made to facilitate prosecution of this application. Applicants reserve the right to pursue any previously pending, or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or in any prior prosecution. Accordingly, reviewers of this or any parent, child, or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Conclusion

Applicants submit that all of the Examiner's rejections have been addressed and overcome, and that all claims are allowable over the art of record. Applicants have submitted amendments and arguments believed to be sufficient to overcome all of the outstanding rejections. Consequently, Applicants have not advanced every argument for the allowability of the claims over the references of record. As such, Applicants do not acquiesce to any of the Examiner's statements or characterizations not specifically traversed. Should the Examiner believe that any outstanding issues are resolvable in an Examiner's Amendment, the Examiner is invited to contact the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 01-2215.

Respectfully submitted,
APPLIED MEDICAL RESOURCES

BY 

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